

2014-1159

**United States Court Of Appeals
for the Federal Circuit**

GILEAD SCIENCES, INC.,
Plaintiff/Appellant,

v.

MICHELLE K. LEE,
Deputy Director of the U.S. Patent and Trademark Office,
Defendant/Appellee,

APPEAL FROM THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
IN CASE No. 12-CV-01090-LO-IDD, JUDGE LIAM O'GRADY

GILEAD'S OPENING BRIEF

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CERTIFICATE OF INTEREST

Counsel for Gilead Sciences, Inc., certifies the following:

1. The full name of every party represented by me is: Gilead Sciences, Inc.
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: N/A.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: N/A.
4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Fish & Richardson P.C.: Jonathan E. Singer; Craig E. Countryman; John A. Brennan; and Ahmed J. Davis.

Gilead Sciences, Inc.: Lorie Ann Morgan; Joel B. Silver; and Brandon S. Boss.

Dated: February 24, 2014

/s/ Craig E. Countryman
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STATEMENT OF RELATED CASES

Pursuant to Fed. R. App. P. 47.5, counsel for Gilead Sciences, Inc. states that there have been no prior appeals in or from the same civil action or proceeding in the lower court previously before this or any other appellate court. No case in this or any court will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

This case challenges the U.S. Patent and Trademark Office's patent term adjustment calculation for one of Gilead's patents. The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338 because the patent laws provide that the mechanism for challenging the PTO's decision on patent term adjustment is a civil action in the Eastern District of Virginia. *See* 35 U.S.C. § 154(b)(4)(A).

The district court entered a final judgment October 3, 2013. (A11.) Gilead filed its Notice of Appeal on November 27, 2013, (A132-33), within 60 days of the judgment, making it timely under Federal Rule of Appellate Procedure 4(a)(1)(B).

This Court thus has jurisdiction over the appeal under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUE

This case presents a single issue of statutory interpretation that will have a profound effect on the strength of the patent incentive. The PTO admits it caused 616 days of delay while examining Gilead's U.S. Patent 8,148,374, a patent that covers a key ingredient in Stribild®, an HIV medication. The PTO has never asserted that Gilead's actions during prosecution caused any delay in patent issuance. Yet the PTO reduced the patent term adjustment by 57 days simply because Gilead submitted an information disclosure statement after its response to a restriction requirement. The issue presented by this appeal is:

Does 35 U.S.C. § 154 permit reducing an applicant's patent term adjustment based upon an applicant action that had no impact on when the PTO concluded prosecution?

STATEMENT OF THE FACTS

I. Congress Ensured that PTO Delay Does Not Reduce Patent Term, While Penalizing “Egregious” Applicant Actions That Actually Cause Delay.

In 1994, Congress changed the U.S. patent term from 17 years from issuance to 20 years from filing. *See* Pub. L. No. 103-465, 108 Stat. 4809 (Dec. 8, 1994). That created a potential problem—PTO delays in examining patents might decrease patent life. Congress addressed this problem in 1999 by enacting the American Inventors Protection Act (AIPA). The Act requires the PTO to adjust a patent’s term when it unreasonably delays the patent’s examination. *See* 35 U.S.C. § 154(b)(1). Three general categories of PTO delay trigger an adjustment—(A) untimely responses to an applicant’s submissions; (B) failure to issue a patent within 3 years of filing; and (C) delays from interferences, secrecy orders, and successful appeals. *See* 35 U.S.C. § 154(b)(1)(A), (B), and (C). Each day of delay triggers one day of term extension. *Id.*

Congress wanted to ensure, however, that applicants could not game the system and accrue patent term adjustment by dragging their feet before the PTO. So Congress provided that adjustments for PTO delay would be offset by each day of delay caused by an applicant’s failure “to engage in reasonable efforts to conclude prosecution”:

The period of adjustment of the term of a patent under paragraph (1) [*i.e.*, the adjustment for PTO delay] shall be reduced by a period equal to ***the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.***

35 U.S.C. § 154(b)(2)(C) (emphasis added).

Congress intended the “reasonable efforts” provision to punish only applicant actions that actually cause delay. The provision first appeared in a 1995 bill, shortly after the switch to the 20-year-from-filing term. *See* Moorhead-Schroeder Patent Reform Act, H.R. 3460, 104th Cong., § 208 (1995). The Judiciary Committee explained that it was meant to punish “egregious and obvious delay tactics” by ensuring that applicants were not rewarded for “intentional or unjustifiable delay”:

Section 154(b)(2)(B) provides that extensions will not be granted where the patent applicant fails to take reasonable efforts to conclude prosecution of the application. The few applicants ***who engage in intentional or unjustifiable delay will not be rewarded for such behavior.*** The PTO is required to prescribe the regulations necessary to carry out the mandate of this subsection. . . . The “reasonable efforts” clause is an effort to avoid the submarine patent problem. The intent of the Committee is that ***only the most egregious and obvious delay tactics will go unrewarded by this provision.***

See H.R. Rep. No. 104-784 at 67 (1995). A 1997 bill in the next Congress contained the same provision and the same commentary. *See* H.R. Rep. No. 105-39 at 66 (1997).

In 1999, the AIPA carried forward the same “reasonable efforts” provision. Congress again stressed that adjustments for PTO delay are offset only by applicant actions that, not only actually cause delay, but purposely manipulate the system:

Only those who purposely manipulate the system to delay the issuance of their patents will be penalized under Title III [which included 35 U.S.C. § 154(b)(2)], a result that the Committee believes entirely appropriate.

H.R. Rep. No. 106-287 at 50 (1999); *see also* H.R. Rep. No. 106-464 at 125 (1999) (same). Thus, the “reasonable efforts” provision was to be used only in limited circumstances of intentional applicant behavior that actually causes delay.

II. Most of the PTO's Implementing Regulations Offset Adjustment by Only Applicant Actions That Actually Cause Delay.

The AIPA instructed the PTO to issue regulations identifying “the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application,” and the PTO has done so. *See* 35 U.S.C. § 154(b)(2)(C)(iii); 37 C.F.R. § 1.704(c). The PTO's explanation for its regulations suggests it has tried to identify applicant behavior that actually causes delay—the PTO has targeted circumstances that “interfere with the Office's ability to process or examine an application.” *Final Rule: Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 Fed. Reg. 56366, 56372 (Sept. 18, 2000).

Consistent with that explanation, most of the PTO's regulations penalize applicant behavior that causes actual delay. The regulations address situations in which the PTO must wait for the applicant to act before it can continue examining the application. *See, e.g.*, 37 C.F.R. § 1.704(c)(1)-(7), (9). When the applicant is late in taking the required action, this causes actual delay, and the PTO reduces any patent term adjustment by the number of days the applicant is late. *Id.* For example, if an applicant asks the PTO to suspend prosecution, any patent term adjustment for PTO delay is reduced by the period in which prosecution was suspended. 37 C.F.R. § 1.704(c)(1). As the PTO's commentary explains, “[o]bviously, if an action is suspended at the applicant's request, the Office is precluded from processing or examining the application as a result of an action by the applicant.” 65 Fed. Reg. at

56,371. The reduction corresponds to that delay—if the applicant asks prosecution to be suspended for 30 days, the term adjustment is reduced by 30 days. *Id.*

But this appeal involves a different kind of regulation—one that applies where the PTO need not wait for the applicant before it can act. Instead, the regulation broadly penalizes applicants almost anytime they file a supplemental paper:

Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

37 C.F.R. § 1.704(c)(8).

The PTO's asserted rationale for this rule is that submission of a supplemental paper requires the Office to restart its consideration of the application:

The submission of a supplemental reply or other paper (e.g., an information disclosure statement (IDS) or petition) after an initial reply was filed requires the Office to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the Office's response to the initial reply.

65 Fed. Reg. at 56372. But the PTO applies this regulation even where the supplemental paper causes no delay, such as when the applicant files it before the examiner has begun work on the Office's response. And unlike the other regulations, the penalty does not correlate to whatever actual delay the applicant might cause—it is measured not by extra time the examiner spends on the application, but instead by the number of days between the applicant's initial and supplemental submissions. *Id.*

III. The PTO Penalized Gilead for Filing a Supplemental Information Disclosure Statement That Caused No Delay.

This appeal is about how the patent term adjustment statute applies to Gilead's U.S. Patent No. 8,148,374. The '374 patent covers the compound cobicistat, along with pharmaceutical compositions (such as Stribild®), and methods for using it to treat HIV.

The timing of relevant events during prosecution is not disputed. Gilead filed the application that became the '374 patent on February 22, 2008. (A12.) The PTO responded with a restriction requirement on November 18, 2009—210 days late under 35 U.S.C. § 154(b)(1)(A)(i)—which directed Gilead to select a subset of the claims for further examination. (A51-60, A16.) Gilead timely responded to the restriction requirement on February 18, 2010, within the 3 month period permitted by 35 U.S.C. § 154(b)(2)(C)(ii), selecting claims for examination. (A68-79, A16.) While waiting for the PTO to issue a first office action on the merits, Gilead filed an information disclosure statement (IDS) on April 16, 2010, which disclosed two other co-pending Gilead patent applications. (A87.)

Nothing in the record suggests that the PTO had started examining the selected claims before Gilead filed the April 16 IDS. In fact, the examiner's notes show her first prior art search was not until April 29, 2010—after the filing of the IDS. (A106.) On May 13, 2010, the examiner timely issued a first office action on the merits, within the 4-month period permitted by 35 U.S.C. § 154(b)(1)(A). (A90-103.)

Prosecution continued, and the '374 patent issued on April 3, 2012. Prosecution took over 3 years, triggering a further adjustment under § 154(b)(1)(B). (A14.)

The parties agree that the various PTO delays resulted in 616 days of term adjustment under 35 U.S.C. § 154(b)(1). (A3-4, A14.) But the PTO docked Gilead 57 days of that adjustment because it thought that Gilead “failed to engage in reasonable efforts to conclude prosecution” by filing the April 16 IDS after its reply to a restriction requirement. (A129-30, *citing* 37 C.F.R. § 1.704(c)(8); A131, A14-16.)

IV. The District Court Accepted the PTO’s Statutory Interpretation.

Gilead challenged the Director’s determination in the Eastern District of Virginia, seeking to recover the 57 days of patent term adjustment. *See* 35 U.S.C. § 154(b)(4)(A) (providing the cause of action). The district court considered cross-motions for summary judgment and ruled for the PTO. (A1-9.)

The district court applied the *Chevron* framework when reviewing the PTO’s application of the patent term adjustment statute to Gilead’s ’374 patent. (A5-9.) Analyzing *Chevron* step 1, the court found that “Congress has not addressed” the question of whether Gilead’s actions constitute applicant-delay, (A5), even though the statutory text, purpose, and history all show that Congress wanted to penalize only egregious applicant actions that actually cause delay. The court also believed it could not resolve the statutory interpretation issue at *Chevron* step 1 because Congress had told the PTO to prescribe regulations, even though Congress limited the PTO to regulating only circumstances that actually cause delay. Turning to *Chevron* step 2, the

court concluded that the PTO reasonably applied 37 C.F.R. § 1.704(c)(8) against Gilead because the “focus of the statute” is “on whether the applicant’s efforts were reasonable, not whether the outcome of those efforts caused actual delay,” (A7), even though the statutory language, history, and purpose show that Congress intended to measure reasonableness based on whether the applicant’s behavior actually caused delay. The court also thought the PTO’s argument that Gilead’s actions could have caused delay was reasonable, (A7-8), despite the absence of any actual delay in this case. The court therefore concluded that Gilead had not shown the PTO’s interpretation was impermissible or unreasonable and granted summary judgment to the Director. (A8-9.)

This appeal followed.

SUMMARY OF THE ARGUMENT

The PTO legally erred when reducing Gilead’s patent term adjustment by 57 days. Properly interpreted, § 154(b)(2)(C)(i) permits reductions only for applicant behavior that delays a patent’s issuance, and Gilead’s behavior did not cause any delay.

As an initial matter, the PTO is not entitled to any deference on this issue of statutory interpretation because Congress’s intent is clear. The statutory text permits reductions for an applicant’s failure to engage in reasonable efforts to “conclude prosecution,” so if an applicant’s conduct does not impact when the PTO “conclude[s] prosecution”—that is, does not cause actual delay—it cannot trigger a reduction. This is consistent with the statute’s purpose, which is to ensure that PTO delays do not cause applicants to lose patent term while not rewarding applicants for delays caused by their own behavior. It is also consistent with how the PTO itself has understood and attempted to justify its regulations implementing the statute. Although the statute permits the PTO to identify the “circumstances” of unreasonable applicant behavior, it can penalize only periods of actual delay.

Moreover, the PTO’s interpretation is unreasonable even if this Court accords it deference. The PTO broadly applies the regulation to situations like Gilead’s, which are outside the regulation’s stated rationale, and it imposes a penalty that far exceeds any actual delay. The PTO’s regulation treats similarly situated applicants differently, contradicts the PTO’s other rules about when an IDS is considered timely, and conflicts with the duty of disclosure. The Court should thus reverse and remand.

STANDARD OF REVIEW

“The correct interpretation of section 154 is an issue of law, which this court decides *de novo*.” *Novartis AG v. Lee*, 740 F.3d 593, 598 (Fed. Cir. 2014). When a court reviews an agency’s statutory construction, it follows the familiar two-step analysis outlined in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984).

The first step is to determine if “Congress’s purpose and intent on the question at issue is judicially ascertainable” using “the traditional tools of statutory construction,” namely “the statute’s text, structure, and legislative history,” and “the relevant canons of interpretation.” *Delverde, SrL v. United States*, 202 F.3d 1360, 1363 (Fed. Cir. 2000); *see also Timex V.I., Inc. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998) (“If the statute’s text does not explicitly address the precise question, we do not at that point simply defer to the agency. Our search for Congress’s intent must be more thorough than that.”). If the Congressional intent is clear, that is the end of the matter and the court must give effect to that intent. *Id.*

If, however, a statute is silent or ambiguous with respect to the specific issue, then the court goes to step two and determines whether the agency’s action is based on a permissible construction of the statute. *Id.* But, even then, the court will defer only if the agency has adopted a “reasonable interpretation” of the statute. *Dominion Resources, Inc. v. United States*, 681 F.3d 1313, 1317 (Fed. Cir. 2012). An agency regulation that reflects an unreasonable interpretation of the statute is invalid and cannot support the agency’s decision. *Id.* at 1318.

ARGUMENT

I. The Statute Permits Reducing Patent Term Adjustment Only When An Applicant Actually Delays the Conclusion of Prosecution.

A. Congress’s Purpose and Intent Was to Penalize Only Applicant Actions that Actually Cause Delay.

The statutory text, purpose, and legislative history all demonstrate that the PTO is permitted to reduce patent term adjustment only when an applicant’s behavior actually delays the conclusion of prosecution. The PTO’s other regulations confirm that this was Congress’s intent, and that the regulation at issue here is an outlier. This Court should therefore adopt that interpretation as a matter of law under *Chevron* step 1, without any deference to the PTO’s contrary interpretation. *See, e.g., Novartis*, 740 F.3d at 601 (adopting the construction that “is supported by the statutory purpose and other aspects of the statutory structure”); *Chevron*, 467 U.S. at 842-43 (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

1. The Statutory Text, Purpose, and Legislative History Demonstrate that Congress Intended to Punish Only Applicant Behavior that Causes Actual Delay.

The statutory text permits reductions only for applicant behavior that actually delays the patent’s issuance. In particular, the statute provides that any term adjustment for PTO delay will be reduced by “the period of time during which the applicant failed to engage in *reasonable efforts to conclude prosecution* of the application.” 35 U.S.C. § 154(b)(2)(C)(i) (emphasis added). Reasonableness derives

its meaning from context. The surrounding statutory language provides the context: an applicant's efforts can be deemed unreasonable only when they impact when the PTO can "conclude prosecution." Likewise, when applicant behavior has no impact on when the PTO "conclude[s] prosecution"—*i.e.*, when it does not actually delay the patent's issuance—there is no statutory basis for reducing an applicant's patent term based on that behavior. Nothing in the statute suggests any other method of measuring the reasonableness of an applicant's behavior other than determining whether it has an effect on when prosecution ends. No statutory goal is furthered by reducing patent term adjustment for applicant action that causes no delay in patent issuance.

Another statutory provision confirms Congress's intent to tie the "reasonable efforts" clause to applicant behavior that causes actual delay. Congress identified one specific type of applicant behavior as a failure "to engage in reasonable efforts to conclude processing or examination" of the application—taking over 3 months to respond to an office action. *See* 35 U.S.C. § 154(b)(2)(C)(ii). This targets only applicant behavior that actually causes delay: the PTO can't conclude prosecution while it is waiting for the applicant to respond, so the applicant is causing actual delay by not responding sooner. Moreover, the penalty fits the offense—the applicant loses one day of adjustment for each day it waits because each day of waiting is another day the PTO can't resume work and conclude prosecution of the application.

Accordingly, the general provision in § 154(b)(2)(C)(i) should be construed consistently with this example to permit reductions for only applicant behavior that causes actual delay, with the reduction being equal to the exact amount of delay caused. *See, e.g., Micron Tech., Inc. v. United States*, 243 F.3d 1301, 1308 (Fed. Cir. 2001) (“Application of the interpretive rule of *ejusdem generis* to § 1677a(d)(1) suggests that Congress intended subsection D to encompass the same types of expenses as are included in subsections A, B and C.”).

The legislative history—and its explanation of the statute’s purpose—confirm that the “reasonable efforts” provision is meant to penalize only applicant behavior that actually causes delay. Congress enacted the AIPA to “compensate patent applicants for certain reductions in patent term” caused by PTO delays “that are not the fault of the applicant.” H.R. Rep. No. 106-287 at 49-50 (1999). But Congress did not want to compensate applicants for delays that are their own fault. So Congress adopted the “reasonable efforts” clause, which was first introduced in the 1995 and 1997 precursors to the AIPA, to ensure that those “who engage in *intentional* or unjustifiable *delay* will not be rewarded” and that “only the most egregious and obvious *delay tactics* will go unrewarded by this provision.” H.R. Rep. No. 104-784 at 67 (1995) (emphasis added); *see also* H.R. Rep. No. 105-39 at 66 (1997). When passing the AIPA in 1999 (and carrying forth the same “reasonable efforts” provision), Congress again stressed that “only those who purposely manipulate the system *to delay the issuance of their patents* will be penalized.” H.R. Rep. No. 106-287 at 50 (1999)

(emphasis added); *see also* H.R. Rep.106-464 at 125 (1999) (same). Every indication, then, is that Congress wanted reductions for only intentional behavior by applicants that actually causes delay in patent issuance. Applicant behavior that does not cause delay, and is not intentional, was not meant to trigger reductions.

Congress's statutory directive to the PTO further demonstrates that it intended to penalize only applicant behavior that causes actual delay. Congress instructed the PTO to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). Applicant behavior only impacts when the PTO can "conclude processing or examination of the application" if it actually causes delay. Therefore, the PTO's role is strictly limited to identifying "circumstances" where an applicant's behavior actually causes delay. The PTO is not permitted to penalize applicants for behavior that does not cause delay.

2. The PTO's Regulations Confirm That Congress Intended to Punish Only Applicant Behavior That Causes Actual Delay.

The traditional tools of statutory interpretation demonstrate that Congress's intent was to penalize only applicant behavior that causes actual delay. In addition, the PTO's own regulations and statements confirm this understanding of Congressional intent.

The PTO has, for the most part, established regulations that impose reductions for applicant acts that actually cause delay. *See, e.g.*, 37 C.F.R. § 1.704(c)(1)-(7), (9). In

particular, the PTO has identified several circumstances where it cannot act on an application because it is waiting for the applicant to do something. These include situations where the applicant has requested the PTO to suspend examination or to defer issuance of the patent, has abandoned an application and later seeks to revive it, or has submitted an incomplete reply. *Id.* These actions actually cause delay because the PTO cannot continue examining the application until it hears further from the applicant. The ball is in the applicant's court, so any delay is the applicant's fault.

The PTO has even tailored its enforcement of another regulation after realizing it would sweep in applicant behavior that does not actually cause delay. 37 C.F.R. § 1.704(c)(10), as written, broadly penalizes applicants for filing any paper after a notice of allowance. But the PTO soon recognized that not all post-allowance submissions cause delay, so it subsequently explained that it will only apply the regulation to the subset of papers that actually cause delay:

After a “Notice of Allowance” has been mailed, submissions by an applicant that cause a delay in processing or examination of an application will be considered a “failure to engage in reasonable efforts” to conclude prosecution. . . .

It should be noted, however, that only certain papers (not all papers), filed after a “Notice of Allowance” is mailed, cause substantial interference and delay in the patent issue process. Therefore, it is the filing of these papers that will be considered a “failure to engage in reasonable efforts” to conclude processing and examination of an application under 37 CFR 1.704.

See Clarification of 37 C.F.R. § 1.704(c)(10), 1247 Official Gazette Patent Office 111 (June 26, 2001), available at <http://1.usa.gov/1grsgEb> (last visited Feb. 24, 2014).

The PTO's stated rationale for the regulation at issue here, 37 C.F.R. § 1.704(c)(8), is that submission of a supplemental paper causes actual delay because the examiner has to restart consideration of the application. *See* 65 Fed. Reg. at 56,372. The problem is that the PTO has used too blunt a tool— a supplemental paper does not necessarily cause delay, yet the PTO applies the regulation in every circumstance, regardless of whether there is actual delay. Nevertheless, the PTO's attempt to justify the regulation by tying it to delay confirms what is plain from the statute's text, purpose, and history: an applicant's patent term adjustment may be reduced only when the applicant's behavior actually delays when the PTO can conclude processing and examining the application. Because Congressional intent is clear, the Court should adopt that interpretation of the statute at *Chevron* step 1. *See, e.g., Wyeth*, 591 F.3d at 1371.

B. The PTO's Interpretation Is Unreasonable in Any Event.

Even under a *Chevron* step 2 analysis, the PTO's application of 37 C.F.R. § 1.704(c)(8) cannot stand. The discussion so far demonstrates that any gap or ambiguity left by Congress has only one reasonable resolution—reductions cannot apply to applicant actions that do not cause actual delay in concluding prosecution. Several additional considerations further demonstrate the unreasonableness of the PTO's interpretation.

First, the PTO's application of § 1.704(c)(8) imposes a penalty in cases that do not fit within the PTO's stated rationale for the regulation. The PTO asserts that a

supplemental IDS causes a delay in examination because it requires the examiner to restart consideration of the application. *See* 65 Fed. Reg. at 56372. That may be true in the rare case in which the supplemental IDS is submitted at the same time the examiner happens to be working on the application. But the PTO applies that regulation to impose a reduction in almost *every* case with a supplemental IDS (the only exception being for submission of limited information received from a patent office within the previous thirty days), regardless of whether the examiner has started reviewing the application before the supplement. *See* 37 C.F.R. § 1.704(c)(8), (d).

This application is impermissibly overbroad—Congress did not intend for the PTO to sweep in applicants whose actions do not actually cause delay. Under the PTO’s regulation, an applicant who submits her response to a restriction requirement on a Friday at 4:00 PM, and then an IDS on a Monday at 9:00 AM loses three days of patent term. Such a result cannot be a reasonable interpretation of Congress’s clearly expressed intent.

Second, in the rare case in which a supplemental paper actually causes delay in concluding prosecution of an application, the penalty imposed by § 1.704(c)(8) does not correlate to the amount of delay. The problem arises because, unlike many of the other circumstances the PTO rightly penalizes, this is not a situation in which the PTO is waiting on the applicant to act before the PTO can continue processing the application. In the event that a supplemental paper were to delay an examiner’s consideration of an applicant’s initial response, the amount of delay caused would be

the same regardless of how long he waits to file the supplemental paper after the filing of the initial response. Yet the PTO penalizes the applicant based on the number of days between the initial and supplemental responses, not the amount of any actual delay (i.e., the actual amount of additional time the examiner spent reviewing the application).

An example may help illustrate the disconnect that exists between the penalty and the amount of actual delay. Suppose that the applicant files a supplemental IDS one month after the initial response, and that this submission causes the examiner to spend an extra day on the file because she received it just as she was in the middle of reviewing the file. The PTO imposes a one month penalty, even though there was only a one-day delay. *Id.* That result is contrary to Congress's goal of day-for-day patent term restoration, making it an impermissible implementation of the statute. *See, e.g., Dominion Resources*, 681 F.3d at 1317 (finding a regulation impermissible under Chevron step 2 where it "directly contradicts" the "rule that Congress intended the statute to implement").

Third, the PTO's regulation is unreasonable because it treats similarly situated applicants differently. Some background is necessary to put the problem in context. Before the PTO begins examining a patent application on the merits, the PTO sometimes issues a "restriction requirement," directing the applicant to elect a subset of the claims for examination. *See generally* 35 U.S.C. § 121; 37 C.F.R. §§ 1.141, 1.142. This might occur if the applicant has submitted claims directed to "two or more

independent and distinct inventions.” 37 C.F.R. § 1.142(a). The applicant must respond by picking a set of claims to pursue, and, after the PTO receives that election, it begins examining only the elected claims. But not all applicants receive a restriction requirement. Those that do receive a restriction receive it before any examination on the merits—the purpose of the restriction is to limit the material the PTO must review in a single patent application. *See, e.g.*, MPEP § 609 (contrasting a restriction from an office action on the merits).

The PTO’s application of 37 C.F.R. § 1.704(c)(8) unreasonably treats applicants who receive a restriction requirement differently from those who do not. Again, an example will illustrate. Suppose there are two applicants, one (like Gilead) who receives a restriction requirement and responds, while the other never receives a restriction requirement. Suppose also that both applicants file an IDS a month before the first office action on the merits. The PTO penalizes the first applicant by treating the IDS as a “supplemental reply” that triggers a reduced adjustment, 37 C.F.R. § 1.704(c)(8), because the IDS came after the response to the restriction requirement. By contrast, the PTO imposes no penalty in the second case.

There is no logical basis for this disparity. Both applicants submitted the IDS in the exact same timeframe before examination on the merits. Both submissions are timely under the PTO’s other regulations governing the submission of an IDS. *See* 37 C.F.R. § 1.97(b)(3) (PTO will consider an IDS filed anytime “before the mailing of a first Office action on the merits” without imposing an additional fee). And both cases

present the same, small chance of minimal delay if the examiner happens to be working on the file when the IDS is received. Yet the PTO imposes no reduction at all in the second case (without the restriction), which strongly suggests that applying its regulation to penalize the first applicant (*e.g.*, Gilead) is arbitrary and unreasonable. *See, e.g., Dongbu Steel Co. v. United States*, 635 F.3d 1363, 1371 (Fed. Cir. 2011) (“We have indicated that an agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently.”).

Indeed, it is doubtful whether an IDS submitted after an applicant’s response to a restriction but before a first office action on the merits is even the type of “supplemental reply or other paper” that should ever trigger 37 C.F.R. § 1.704(c)(8). The applicant’s submission of the IDS is unrelated to her response to the restriction requirement—a restriction narrows the subject matter for examination, so it would not prompt the need to disclose more prior art. Instead, the IDS submission is an independent event that, as the PTO’s other regulations acknowledge, does not cause actual delay when it occurs before a first office action on the merits.

Fourth, the PTO’s application of 37 C.F.R. § 1.704(c)(8) is unreasonable because it creates a conflict between the applicant’s duty of disclosure and duty to move along prosecution to avoid losing patent term. Applicants are required, under 37 C.F.R. § 1.56, to disclose material information to the PTO. Yet, under the PTO’s application of 37 C.F.R. § 1.704(c)(8), applicants have an incentive to avoid submitting an IDS as soon as material information comes to their attention. Another example may help.

Suppose an applicant learns of material information a month after responding to a restriction requirement. If the applicant immediately submits an IDS, she risks a month reduction in term adjustment. But if the applicant waits until after the PTO's first office action on the merits, the applicant can submit an IDS with the next response to office action without triggering a reduction under § 1.704(c)(8) because there is no "supplemental" paper. By this behavior, the applicant avoids a reduction even if the submission triggers a further office action and actually delays prosecution. Therefore, the PTO's application of 37 C.F.R. § 1.704(c)(8) encourages applicants to engage in the very type of dilatory conduct that Congress wanted to eliminate.

The bottom line is that, although the PTO may penalize applicants whose supplemental paper actually causes delay, it cannot punish *all* applicants who file a supplemental paper based on a hypothetical concern about delay. *See, e.g., Novartis*, 740 F.3d at 602 ("The possible existence of these exceptional cases does not support a general rule excluding time between allowance and issuance. *In the present case*, time after allowance was not time caused by the continued examination."). Instead, the PTO must identify the applicant actions that actually cause delay and punish only those specific actions or circumstances. And the PTO may not punish any applicant for more than the actual delay her actions caused.

The PTO could easily administer such a system. One fix would be to narrow 37 C.F.R. § 1.704(c)(8) to make clear that an IDS submitted after a response to a restriction but before the first office action on the merits is not a "supplemental reply

or other paper.” This could be readily applied across all cases, and it would eliminate the disparity of the current regime by treating every IDS submitted before the first office action the same way—as a timely submission.

Another broadly applicable alternative would be for the PTO to require that the examiner note in the file history when she began reviewing the applicant’s submissions. Examiners already make similar types of notes—the examiner here indicated when she ran a prior art search and when she reviewed some of the IDS submissions (A106)—so requiring the examiner to note when she began reviewing the file would impose a minimal burden. The PTO could then use the information about when the examiner began review to determine if the supplemental IDS caused any actual delay. If the supplemental IDS were filed before the examiner began review, there would be no delay and thus no penalty. If the supplemental IDS were filed after the examiner began review, the penalty would be the number of days the examiner was delayed in completing her review.

Therefore, the PTO’s application of 37 C.F.R. § 1.704(c)(8) to penalize applicant behavior that does not actually delay prosecution, and to impose a penalty that bears no relation to the amount of delay that could even theoretically be caused, is an impermissible and unreasonable application of the statute even if the PTO receives deferential review under *Chevron*.

II. The PTO Should Not Have Penalized Gilead Because There Was No Actual Delay in this Case.

When the Court properly interprets § 154(b)(2)(C)(i) to permit reductions of term adjustment only where the applicant's behavior caused actual delay, the result in this case is straightforward. Gilead's supplemental IDS caused no actual delay, and the PTO has never said otherwise. Therefore, the PTO incorrectly reduced Gilead's patent term adjustment by 57 days.

The facts of this case further underscore how the PTO's application of 37 C.F.R. § 1.704(c)(8) conflicts with Congressional intent. The PTO penalized Gilead for the period between its initial response to the restriction requirement on February 18, 2010 and its IDS on April 16, 2010. (A16.) But the PTO did not even forward Gilead's initial response to the examiner until March 12—over 3 weeks after it was filed. (A16.) The examiner did not conduct her first prior art search until April 29, 2010—nearly 2 weeks *after* Gilead's IDS. (A106.) The examiner did not consider any of Gilead's disclosure statements until May 11, 2010—well after the April 16 submission. (A107-17.) In fact, although made of record in the file, the examiner did not even sign and date the April 16 IDS. (A87; *see also* A92, A16.) So Gilead was penalized for 22 days during which the examiner could not have picked up the file, and another 35 days in which all the evidence suggests the examiner did not pick up the file. It instead appears that the examiner started work on Gilead's application only after the April 16 IDS, and never had to restart or duplicate efforts. The PTO

therefore erred in reducing Gilead's term adjustment at all because there was no evidence of actual delay. And the error is particularly troubling because Gilead's conduct was nothing like the "egregious" and "intentional" behavior that Congress intended the "reasonable efforts" provision to penalize.

Moreover, the penalty here far exceeded any even theoretical delay. The PTO penalized Gilead for 57 days. Yet the time between Gilead's supplemental IDS (on April 16) and the examiner's office action (on May 13) was only 27 days. So even if Gilead's supplemental IDS somehow caused the examiner to work every day from the day she received it until the time she mailed an office action, the maximum potential delay was 27 days, less than half the time that the PTO penalized Gilead.

All of this further demonstrates that Congress meant what it said in passing § 154(b)(2)(C)— the PTO may punish only actual delay, and may not write regulations that broadly sweep in conduct that does not cause delay (like Gilead's IDS submission here) in an effort to penalize the other applicants whose "intentional" and "egregious" delay tactics Congress did not want to reward.

CONCLUSION

For the reasons above, the Court should reverse and remand with instructions to set the patent term adjustment for the '374 patent to 616 days, eliminating the 57 day reduction for behavior that did not actually delay the conclusion of prosecution.

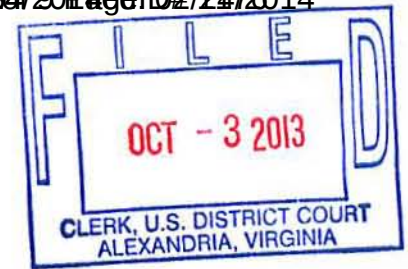
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ADDENDUM



IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

GILEAD SCIENCES, INC.,

Plaintiff,

-v-

TERESA STANEK REA,
Acting Undersecretary of Commerce for
Intellectual Property and Acting Director of
United States Patent and Trademark Office,

Defendant.

Civil Action No. 1:12-cv-1090

MEMORANDUM OPINION

This matter comes before the Court on the parties' cross-motions for summary judgment (Dkt. Nos. 11 and 15). Plaintiff Gilead Sciences, Inc. ("Gilead") asks the Court to find that the Defendant United States Patent and Trademark Office ("USPTO") improperly calculated the patent term adjustment for the U.S. Patent No. 8,148,374 ("the '374 patent"). The cross-motions for summary judgment were opposed and argument on the matter was held on July 19, 2013. The facts in this case are undisputed and the legal disagreement between the parties is narrow, namely whether the USPTO's construction of 35 U.S.C. § 154(b)(2)(C) is permissible. For the reasons that follow, the Court finds that the Defendant is entitled to judgment as a matter of law.

I. BACKGROUND

a. Statutory Framework

To acquire a patent, an applicant must submit an application with the USPTO. 35 U.S.C. § 111. The USPTO then examines the application to determine whether the applicant is entitled to a patent. *Id.* at § 131. If the USPTO determines that the application claims "two or more

independent and distinct inventions,” the office may mandate that the application be restricted to one of the inventions. *Id.* at § 121. This is commonly referred to as a restriction requirement. Upon examination, notification of a restriction requirement must be sent to the applicant in the same manner as notification of a rejection or other objection to the application. *Id.* at § 132. If the USPTO determines at any time during the examination that an application is patentable it will likewise notify the applicant of the allowance. 37 C.F.R. § 1.311(a). Throughout the application process, an applicant has a duty to disclose “all information known to that individual to be material to patentability.” *Id.* at § 1.56(a). One way in which an applicant meets this duty to disclose is through the filing of an information disclosure statement (“IDS”).

The law governing the content and term of a patent is outlined in 35 U.S.C. § 154. Under §154 a patent grant is issued for twenty years measured from the earliest filing date of the application. *Id.* Understanding that delays in the examination process might decrease the length of a patent term, Congress created provisions under which a patent owner can seek a patent term adjustment (“PTA”) for certain delays caused by the USPTO between the filing and issuance of a patent. Section 154(b)(1) outlines the general sources of delay for which a PTA can be sought. The first, commonly referred to as “A Delay,” allows for a patent term extension if the USPTO fails to provide a notification under §132 or a notice of allowance within fourteen months of an application filing. 35 U.S.C. § 154(b)(1)(A)(i). The second, commonly referred to as “B Delay,” allows for a one day extension for every day that the USPTO fails to issue a patent after three years have passed between the application and allowance dates. *Id.* at § 154(b)(1)(B). Finally, a “C Delay” allows a PTA for some types of delays excluded from the computation of a “B Delay.” *Id.* at § 154(b)(1)(C).

An applicant's conduct also impacts the calculation of a PTA. In particular, a PTA is reduced by a period of time equal to the number of days which an applicant "failed to engage in reasonable efforts to conclude prosecution of the application." *Id.* at § 154(b)(2)(C)(i). Congress has explicitly directed the USPTO to issue regulations establishing what constitutes an applicant's failure to engage in such reasonable efforts. *Id.* at § 154(b)(2)(C)(iii). The application of regulations promulgated by the USPTO pursuant to this mandate is the focus of the controversy before the Court.

b. Material Facts

The facts in this case are not in dispute. On February 22, 2008, Gilead filed application number 12/036,124 with the USPTO. On November 18, 2009, the USPTO mailed a restriction requirement to Gilead, dividing the claims within the application into four groups of inventions and directing Gilead to select one for examination. On February 18, 2010, Gilead filed a response to the restriction requirement selecting one of the four groups for examination on the merits. On April 16, 2010, approximately two months after the USPTO received a response to the restriction requirement, Gilead filed a supplemental IDS. The IDS requested that the USPTO consider two additional co-pending patent applications owned by Gilead as part of the agency's next office action. After further prosecution of the application, the USPTO issued a notice of allowance on July 29, 2011 and the '374 patent issued on April 3, 2012.

The parties agree that Gilead is entitled to a PTA as a result of USPTO's failure to meet the timeliness requirements of §154 in issuing the '374 patent. In calculating the appropriate PTA, the USPTO included 245 days of "A Delay" for the Office's failure to meet the specific statutory response deadlines and 406 days of "B delay" for the Office's failure to issue the patent within three years of the application's filing date. Those 651 combined days were reduced by 35

days of overlapping delay, for a cumulative USPTO delay of 616 days. The USPTO further reduced the PTA by subtracting an additional 57 days for Gilead's delay. This 57-day penalty was based on the period between Gilead's initial reply to the restriction requirement and its filing of the additional IDS on April 16, 2010. With all of the delays accounted for, the USPTO calculated a total PTA of 559 days.¹

On October 27, 2011, Gilead contested the 57-day assessment for applicant delay, arguing that its delay in filing the supplemental IDS should not be subtracted from the PTA. The USPTO rejected this argument on March 1, 2012, reasoning that "under 35 U.S.C. § 132, the first action mailed by the USPTO was the restriction requirement mailed November 18, 2009." *See* Dkt. No. 16 at 12-13. Under this interpretation Gilead's filing of a supplemental IDS after it had filed a response to the restriction requirement constituted a failure to engage in a reasonable effort to conclude prosecution as dictated by 37 C.F.R. § 1.704(c)(8).

Gilead filed the current action before the Court after the USPTO refused to reverse its PTA calculation for the '374 patent. In particular, Gilead complains that the USPTO's interpretation and application of §154(b), which resulted in the 57-day assessment for applicant delay, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation." *See* Dkt. No. 1 at ¶ 28. *See also* 5 U.S.C. §§ 701-706.

The parties filed cross-motions for summary judgment, agreeing that only questions of law were in dispute. The Court heard argument from the parties in open court on July 19, 2013 and took the matter under advisement.

¹ The full calculation for the PTA in this case was: 245 days of A Delay + 406 days of B Delay – 35 days of overlapping USPTO delay – 57 days of applicant delay = 559 days.

II. ANALYSIS

a. Standard of Review

Summary judgment is appropriate where there are no genuine issues of material fact and the reviewing court finds that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The USPTO’s patent term adjustment decisions are reviewed under the Administrative Procedure Act (“APA”). See 35 U.S.C. § 154(b)(4)(A). Under the APA, this Court can only set aside the USPTO’s action if it was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). The Court’s review is therefore limited to the task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment. *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006).

b. *Chevron*

The parties agree that the *Chevron* two-step analysis applies to this case. The first step requires the Court to determine if Congress has spoken to the precise question at issue. *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984). Here the precise issue is whether filing a supplemental IDS after submitting a reply to a restriction requirement constitutes a failure “to engage in reasonable efforts to conclude prosecution of the application.” Contrary to Gilead’s far-reaching argument, Congress has not addressed this question. In fact Congress explicitly directed the USPTO to “prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii). The Court must therefore turn to the second step of the *Chevron* framework. This leaves one narrow question for the Court to decide: is the

USPTO's construction and application of the statute permissible? *See Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 843 (1984) ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.").

c. USPTO's Construction is Permissible

As dictated by Congress, the USPTO promulgated regulations identifying what circumstances "constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application." 37 C.F.R. 1.704. In its letter to Gilead denying reconsideration of its PTA decision, the USPTO stated that the submission of Gilead's supplemental IDS constituted applicant delay pursuant to 37 C.F.R. § 1.704(c)(8). That regulation lays out a particular circumstance amounting to an unreasonable effort by an applicant under § 154(b)(2)(C):

Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the day after the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

37 C.F.R. § 1.704(c)(8). Gilead's filing of a supplemental IDS after it sent its reply to the restriction requirement fits squarely within the circumstance outlined in §1.704(c)(8). Gilead's contention, therefore, is that §1.704(c)(8) itself constitutes an impermissible construction of the statute.

Gilead primarily argues that the USPTO's interpretation under §1.704(c)(8) is unreasonable because it penalizes a group of applicants who have not caused an actual delay in the examination process. Gilead contends that allowing the USPTO to interpret the statute such

that the agency penalizes applicants who have not caused an actual delay leaves the USPTO without any boundaries in issuing regulations under §154(b)(2)(C). This line of argument is unavailing. Congress clearly intended for the USPTO to use its expertise and experience in dictating what circumstances demonstrate a lack of reasonable effort on the part of an applicant. The explicit focus of the statute therefore is on whether the applicant's efforts were reasonable, not whether the outcome of those efforts caused actual delay.²

Moreover, the USPTO has demonstrated that the conduct penalized under 37 C.F.R. § 1.704(c)(8) amounts to behavior that interferes with the Office's ability to process an application. As the USPTO explains, an examiner must review an application before issuing a restriction requirement. After receiving a reply to the restriction requirement the examiner will continue his or her review of the application. Receiving relevant information after a reply to a restriction requirement clearly interferes with an examiner's ability to conclude the prosecution of the application, particularly when §154 penalizes the USPTO if the examiner fails to do so within four months of the applicant's reply. 35 U.S.C. § 154(b)(1)(A)(ii). It is reasonable to conclude that an examiner reviewing Gilead's application would be delayed by learning of the existence of material information fifty-seven days after receiving the company's response to his or her restriction requirement. This argument, of course, is limited to viewing Gilead's application in total isolation. As the USPTO also shows, "a supplemental reply or paper often causes delay not only in processing an examination of the particular applicant's application, but also with the processing and examination of other applications before the examiner." *See* Dkt.

² Tellingly, at no point does Gilead attempt to explain why it did not include the information relating to *its own co-pending applications* when it replied to the restriction requirement, opting instead to wait fifty-seven days before notifying the USPTO of information it had been in possession of for approximately a year prior. Notwithstanding its theoretical argument about hypothetical non-delays, Gilead fails to show how its failure to disclose this information when it initially responded to the restriction requirement was reasonable.

No. 19 at 6. The USPTO's concerns are reasonable and do not show an arbitrary and capricious application of the statute.

Gilead also argues that the USPTO's interpretation is impermissible because a restriction requirement is not a final action on the merits. Because of this, Gilead contends, it makes no sense to penalize an applicant for submitting a supplemental IDS before the USPTO mails its first office action on the merits. *See* Dkt. No. 13 at 8. Gilead concedes, however, that a restriction requirement is clearly an office action. *See* 35 U.S.C. § 132. *See also Univ. of Massachusetts v. Kappos*, 903 F. Supp. 2d 77, 87 (D.D.C. 2012) ("Plaintiffs do not dispute, nor can they, that 'an action' is clearly defined under 35 U.S.C. § 132 as a rejection, an objection, or a requirement."). There is also no debate that an applicant's reply to a restriction requirement triggers the four-month clock for measuring the "A Delay." *See* 35 U.S.C. § 154(b)(1)(A)(ii). A supplemental IDS, such as the one that Gilead submitted, forces an examiner to *go back* and review the application again, while still trying to meet his or her timeliness obligations under §154. It is reasonable to penalize an applicant for actions that could lead to this result.

None of this is to say that an applicant who submits a supplemental IDS after replying to a restriction requirement will always be penalized. Under 37 C.F.R. § 1.704(d) there is no PTA reduction when an applicant promptly provides an IDS containing information recently acquired through communication from the USPTO or a foreign patent office. The USPTO has determined, however, that when an applicant sits on material information in its possession, after replying to a restriction requirement, with no good excuse for having done so, it has failed to engage in "reasonable efforts to conclude processing or examination of an application." This interpretation of the statute is both reasonable and permissible.

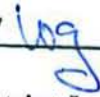
To conclude its arguments, Gilead highlights a number of policy disagreements in order to demonstrate the impermissibility of the USPTO's interpretation. This Court, however, need not assess such policy disputes at step two of the *Chevron* framework. See *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980-82 (2005) (filling statutory gaps "involves difficult policy choices that agencies are better equipped to make than courts" (citing *Chevron*, 467 U.S. at 865-866)). Even if this Court believed Gilead's interpretation is more reasonable than the USPTO's, Plaintiff would still fail. *Id.* ("*Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation."). Gilead can only succeed by showing that the USPTO's interpretation is unreasonable. *Chevron*, 467 U.S. at 844. Gilead has failed to do so.

III. Conclusion

For the reasons set forth above, the Court finds that the USPTO's interpretation of the statute is permissible. It is therefore **ORDERED** that Gilead's Motion for Summary Judgment (Dkt. No. 11) is **DENIED** and the USPTO's Motion for Summary Judgment (Dkt. No. 15) is **GRANTED**.

An appropriate Order shall issue.

Oct 3, 2013

/s/ 

 Liam O'Grady
 United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division



GILEAD SCIENCES, INC.,

Plaintiff,

-v-

TERESA STANEK REA,
Acting Undersecretary of Commerce for
Intellectual Property and Acting Director of
United States Patent and Trademark Office,

Defendant.

Civil Action No. 1:12-cv-1090


ORDER

This matter comes before the Court on the parties' cross-motions for summary judgment (Dkt. Nos. 11 and 15). The Court held a hearing on the cross-motions on July 19, 2013.

For the reasons stated in the accompanying Memorandum Opinion, and for good cause shown, it is hereby **ORDERED** that:

1. Plaintiff's Motion for Summary Judgment (Dkt. No. 11) is **DENIED**;
2. Defendant's Cross Motion for Summary Judgment (Dkt. No. 15) is **GRANTED**;
- and
3. The Clerk shall enter judgment pursuant to Fed. R. Civ. P. 56.

October 3, 2013
Alexandria, Virginia

/s/ 
Liam O'Grady
United States District Judge

Case 1:12-cv-01090-LO-IDD Document 26 Filed 10/03/13 Page 1 of 1 PageID# 1186

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division



GILEAD SCIENCES, INC.,

Plaintiff,

v.

Civil Action: 1:12cv1090

TERESA STANEK REA,
Acting Undersecretary of Commerce for
Intellectual Property and Acting Director
of United States Patent and Trademark
Office

Defendant.

JUDGMENT

Pursuant to the Order of this Court entered on October 3, 2013, and in accordance with Federal Rules of Civil Procedure 56, JUDGMENT is hereby entered in favor of Defendant, Teresa Stanek Rea, and against Plaintiff, Gilead Sciences, Inc.

FERNANDO GALINDO, CLERK

By: _____ /s/
Deputy Clerk

Alexandria, Virginia
October 3, 2013

CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on February 24, 2014. Counsel was served via CM/ECF.

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CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that the opening brief for Appellant Gilead Sciences, Inc. complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contain 6,059 as determined by Microsoft Word.

Dated: February 24, 2014

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